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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,587	07/10/2003	Claus Herdeis	HERDEIS-2	1287

20151 7590 07/13/2006

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350 FIFTH AVENUE  
SUITE 4714  
NEW YORK, NY 10118

EXAMINER
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GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/616,587	HERDEIS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Isis Ghali	1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>09/08/2003</u> .  | 6) <input type="checkbox"/> Other: ____.                                    |

### **DETAILED ACTION**

The receipt is acknowledged of applicants' IDS filed 09/08/2003.

Claims 1-8 are pending and included in the prosecution.

#### ***Information Disclosure Statement***

1. The information disclosure statement filed 09/08/2003 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. The information referred to therein regarding foreign patents and non-patent literature that have no English abstract or translation has not been considered.

#### ***Specification***

2. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

#### ***Claim Rejections - 35 USC § 102***

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3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3 5, 6, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 1103251 ('251).

US '251 disclosed the use of 1,1-dioxo-perhydro-1,2,4-thiadiazine compounds, i.e. taurolidine, to treat acne. Acne was treated by a gel composition comprising 2% taurolidine. The treatment continued for 3 month till no further treatment was required. (See the provided abstract).

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP '251 in view of US 5,976,565 ('565).

US '251 disclosed the use of 1,1-dioxo-perhydro-1,2,4-thiadiazine compounds, i.e. taurolidine, to treat acne. Acne was treated by a gel composition comprising 2% taurolidine. The treatment continued for 3 month till no further treatment was required. (See the provided abstract).

However, EP '251 does not teach that the composition comprising taurolidine is integrated in medical tape, topical dressing or dermal patch as claimed in claim 4.

US '565 teaches patch for topical application of anti-acne formulation comprising antimicrobial agents (abstract). The patch is simple and comfortable and provides minimal adverse effects and maximum efficacy (col.2, lines 24-27).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat acne by using topical composition comprising taurolidine as disclosed by US '251, and deliver the anti-acne composition in the form of a dermal patch as disclosed by US '565, motivated by the teaching of US '565 that the patch is simple and comfortable and provides minimal adverse effects and maximum efficacy, with reasonable expectation of having patch comprising taurolidine that is simple and comfortable and treats acne effectively with minimal adverse effects.

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8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP '251 in view of 4,938,960 ('960).

US '251 disclosed the use of 1,1-dioxo-perhydro-1,2,4-thiadiazine compounds, i.e. taurolidine, to treat acne. Acne was treated by a gel composition comprising 2% taurolidine. The treatment continued for 3 month till no further treatment was required. (See the provided abstract).

However, EP '251 does not teach unguentum cordes as a carrier for taurolidine as claimed in claim 7.

US '960 teaches composition to treat and protect human skin comprising the conventional carrier unguentum codes as a base for cream (abstract; col.3, lines 62-64).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat acne by using topical composition comprising taurolidine as disclosed by US '251, and use unguentum cordes as a carrier for the topical composition as disclosed by US '960, motivated by the teaching of US '960 that unguentum cordes is a conventional base for cream used for protecting and treating skin, with reasonable expectation of having topical composition for treating acne comprising taurolidine and unguentum cordes that treat acne effectively and safely.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,350,742 disclosed treatment of ear infection caused by

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gram-negative and gram-positive bacteria using topical formulation comprising from 0.5 to 2.0% taurolidine (abstract; col.2, lines 33-64; col.6, lines 17-25).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis Ghali  
Examiner  
Art Unit 1615

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*Isis Ghali*  
EXAMINER